

Appl. No. : **10/665,203**
Filed : **September 18, 2003**

AMENDMENTS TO THE CLAIMS

1-29. (CANCELLED)

30. (PREVIOUSLY PRESENTED) A composition comprising rapamycin and a second component comprising polyethylene glycol.

31. (PREVIOUSLY PRESENTED) The composition of claim 30, wherein the second component further comprises ethanol.

32. (PREVIOUSLY PRESENTED) The composition of claim 30 or claim 31, wherein the composition is a solution of rapamycin dissolved in the second component.

33. (PREVIOUSLY PRESENTED) The composition of claim 30 or claim 31, wherein the composition is a suspension of rapamycin in the second component.

34. (PREVIOUSLY PRESENTED) The composition of claim 30, wherein the composition contains an amount of rapamycin effective to treat the wet form of age-related macular degeneration in a human.

35. (PREVIOUSLY PRESENTED) The composition of claim 30, wherein the composition contains an amount of rapamycin effective to prevent the wet form of age-related macular degeneration in a human.

36. (PREVIOUSLY PRESENTED) The composition of claim 35, wherein the composition contains an amount of rapamycin effective to prevent the wet form of age-related macular degeneration in a human having a predisposition to develop the wet form of age-related macular degeneration.

37. (PREVIOUSLY PRESENTED) The composition of claim 30, wherein the composition contains an amount of rapamycin effective to inhibit the transition in a human from

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the dry form of age-related macular degeneration to the wet form of age-related macular degeneration.

38. (PREVIOUSLY PRESENTED) A composition of rapamycin dissolved in polyethylene glycol and ethanol, wherein the composition contains an amount of rapamycin effective to treat the wet form of age-related macular degeneration in a human.

39. (PREVIOUSLY PRESENTED) A polyethylene glycol based ocular composition comprising polyethylene glycol and a therapeutic agent.

40. (PREVIOUSLY PRESENTED) The composition of claim 39, wherein the therapeutic agent is an immunophilin binding active agent.

41. (PREVIOUSLY PRESENTED) The composition of claim 40, wherein the immunophilin binding active agent is selected from the group consisting of rapamycin, tacrolimus, everolimus, pimecrolimus, SDZ-RAD, CCI-779, AP23841, ABT-578, and analogs and derivatives thereof.

42. (PREVIOUSLY PRESENTED) The composition of claim 41, wherein the immunophilin binding active agent is selected from the group consisting of rapamycin, tacrolimus, everolimus, pimecrolimus, SDZ-RAD, CCI-779, AP23841, and ABT-578.

43. (PREVIOUSLY PRESENTED) The composition of claim 42, wherein the immunophilin binding compound is rapamycin.

44. (PREVIOUSLY PRESENTED) The composition of claim 39, further comprising ethanol.

45. (PREVIOUSLY PRESENTED) The composition of claim 39, wherein the polyethylene glycol based ocular composition is a solution in which the therapeutic agent is dissolved in the polyethylene glycol.

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46. (PREVIOUSLY PRESENTED) The composition of claim 39, wherein the polyethylene glycol based ocular composition is a liquid composition.

47. (PREVIOUSLY PRESENTED) The composition of claim 39, wherein the polyethylene glycol based ocular composition is a suspension.

48. (PREVIOUSLY PRESENTED) The composition of claim 39, wherein the polyethylene glycol based ocular composition contains an amount of therapeutic agent effective to treat the wet form of age-related macular degeneration in a human.

49. (PREVIOUSLY PRESENTED) The composition of claim 39, wherein the polyethylene glycol based ocular composition contains an amount of therapeutic agent effective to prevent the wet form of age-related macular degeneration in a human having a predisposition to develop the wet form of age-related macular degeneration.

50. (PREVIOUSLY PRESENTED) The composition of claim 39, wherein the polyethylene glycol based ocular composition contains an amount of therapeutic agent effective to inhibit the transition in a human from the dry form of age-related macular degeneration to the wet form of age-related macular degeneration.

51. (PREVIOUSLY PRESENTED) A method for treating a human having the wet form of age-related macular degeneration, the method comprising administering to the human a composition in an amount effective to treat the age-related macular degeneration, wherein the composition comprises rapamycin dissolved in polyethylene glycol and ethanol.

52. (PREVIOUSLY PRESENTED) The method of claim 51, wherein the composition is administered by placement of the composition into the vitreous of the human.

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53. (PREVIOUSLY PRESENTED) The method of claim 52, wherein the composition is administered by intravitreal injection.

54. (PREVIOUSLY PRESENTED) The method of claim 51, wherein the composition is administered by placement of the composition between the conjunctiva and the sclera of the human.

55. (PREVIOUSLY PRESENTED) The method of claim 54, wherein the composition is administered by subconjunctival injection.

56. (PREVIOUSLY PRESENTED) The method of claim 51, further comprising treating the human with an additional treatment selected from administration of a composition comprising Lucentis, administration of a composition comprising an antibody to the same target as Lucentis, administration of a composition comprising Macugen, and administration of a composition comprising Visudyne™ and treatment with photodynamic therapy.

57. (PREVIOUSLY PRESENTED) A method for preventing the wet form of age-related macular degeneration in a human, the method comprising administering to a human a composition in an amount effective to prevent the wet form of age-related macular degeneration, wherein the composition comprises rapamycin dissolved in polyethylene glycol and ethanol.

58. (PREVIOUSLY PRESENTED) The method of claim 57, wherein the composition is administered by placement of the composition into the vitreous of the human.

59. (PREVIOUSLY PRESENTED) The method of claim 58, wherein the composition is administered by intravitreal injection.

60. (PREVIOUSLY PRESENTED) The method of claim 57, wherein the composition is administered by placement of the composition between the conjunctiva and the sclera of the human.

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61. (PREVIOUSLY PRESENTED) The method of claim 60, wherein the composition is administered by subconjunctival injection.

62. (PREVIOUSLY PRESENTED) The method of claim 57, wherein the method further comprises identifying a human with a predisposition to develop the wet form of age-related macular degeneration and administering the composition to the identified human to prevent the wet form of age-related macular degeneration.

63. (PREVIOUSLY PRESENTED) A method for inhibiting the transition in a human from the dry form of age-related macular degeneration to the wet form of age-related macular degeneration, the method comprising administering to a human having the dry form of age-related macular degeneration a composition in an amount effective to inhibit the transition to the wet form of age-related macular degeneration, wherein the composition comprises rapamycin dissolved in polyethylene glycol and ethanol.

64. (PREVIOUSLY PRESENTED) The method of claim 63, wherein the composition is administered by placement of the composition into the vitreous of the human.

65. (PREVIOUSLY PRESENTED) The method of claim 64, wherein the composition is administered by intravitreal injection.

66. (PREVIOUSLY PRESENTED) The method of claim 63, wherein the composition is administered by placement of the composition between the conjunctiva and the sclera of the human.

67. (PREVIOUSLY PRESENTED) The method of claim 66, wherein the composition is administered by subconjunctival injection.

68. (PREVIOUSLY PRESENTED) A method for treating an angiogenesis-mediated disease or condition of the retina or choroid in a mammal, the method comprising administering to the mammal an effective amount of a composition according to claim 30 or claim 39.

69. (PREVIOUSLY PRESENTED) The method of claim 68, wherein the mammal is a human and the angiogenesis-mediated disease or condition of the retina or choroid is selected from the group consisting of choroidal neovascularization, diabetic retinopathy, macular degeneration, the dry form of age-related macular degeneration, and the wet form of age-related macular degeneration.

70. (PREVIOUSLY PRESENTED) The method of claim 69, wherein the angiogenesis-mediated disease or condition of the retina or choroid is the wet form of age-related macular degeneration.

71. (PREVIOUSLY PRESENTED) The method of claim 68, wherein the composition is administered by placement of the composition into the vitreous of the human.

72. (PREVIOUSLY PRESENTED) The method of claim 71, wherein the composition is administered by intravitreal injection.

73. (PREVIOUSLY PRESENTED) The method of claim 68, wherein the composition is administered by placement of the composition between the conjunctiva and the sclera of the human.

74. (PREVIOUSLY PRESENTED) The method of claim 73, wherein the composition is administered by subconjunctival injection.

75. (PREVIOUSLY PRESENTED) The method of claim 68, further comprising treating the human with an additional treatment selected from administration of a composition comprising Lucentis, administration of a composition comprising an antibody to the same target

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as Lucentis, administration of a composition comprising Macugen, and administration of a composition comprising Visudyne™ and treatment with photodynamic therapy.

76. (New) A method to treat a disease affecting the choroid or retina of an eye in a patient having diabetic retinopathy or age related macular degeneration, the method comprising administering to the eye a composition comprising between 0.25% (w/w) to 2.5% (w/w) of rapamycin in a pharmaceutically acceptable topical formulation for a duration to achieve an amount of rapamycin in the choroid or retina sufficient to treat the disease.

77. (New) The method of claim 76, wherein the composition comprises 0.25% (w/w) of rapamycin.

78. (New) The method of claim 76, wherein the composition comprises 2.5% (w/w) of rapamycin.

79. (New) A method to treat a disease affecting the choroid or retina of an eye in a patient having diabetic retinopathy or age related macular degeneration, the method comprising administering to the eye a composition comprising between 0.1% (w/w) to 2.5% (w/w) of rapamycin in a pharmaceutically acceptable topical formulation for a duration to achieve an amount of rapamycin in the choroid or retina sufficient to treat the disease.

80. (New) The method of claim 79, wherein the composition comprises 0.1% (w/w) of rapamycin.

81. (New) The method of claim 79, wherein the composition comprises 1% (w/w) of rapamycin.

82. (New) A method to treat a disease affecting the choroid or retina of an eye in a patient having diabetic retinopathy or age related macular degeneration, the method comprising administering to the eye a composition comprising between 0.1% (w/w) to 5% (w/w) of

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rapamycin in a pharmaceutically acceptable topical formulation for a duration to achieve an amount of rapamycin in the choroid or retina sufficient to treat the disease.

83. (New) The method of claim 82, wherein the composition comprises 2% of rapamycin.

84. (New) A method to treat a disease affecting at least one of the choroid, retina, or uvea of an eye in a patient having diabetic retinopathy, age related macular degeneration, or retinitis pigmentosa, the method comprising administering to the eye a composition comprising between 0.1% (w/w) to 5% (w/w) of rapamycin in a pharmaceutically acceptable topical formulation for a duration to achieve an amount of rapamycin in the choroid, retina, or uvea sufficient to treat the disease.

85. (New) The method of claim 84, wherein the composition comprises 2% of rapamycin.

86. (New) A method to treat a disease affecting the choroid or retina of an eye in a patient having diabetic retinopathy or age related macular degeneration, the method comprising administering to the eye a composition comprising between 0.1% (w/w) to 5% (w/w) of a therapeutic agent selected from the group consisting of immunophilin binding compounds in a pharmaceutically acceptable topical formulation for a duration to achieve an amount of the therapeutic agent in the choroid or retina sufficient to treat the disease.

87. (New) The method of claim 86, wherein the therapeutic agent is selected from the group consisting of rapamycin, tacrolimus, everolimus, pimecrolimus, SDZ-RAD, CCI-779, AP23841, ABT-578, and analogs and derivatives thereof.

88. (New) The method of claim 87, wherein the therapeutic agent is selected from the group consisting of rapamycin and tacrolimus.

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89. (New) The method of any of claims 86, 87 or 88, wherein the composition comprises 2% of the therapeutic agent.

90. (New) The method of claim 88, wherein the therapeutic agent is tacrolimus and the composition comprises 1% of the therapeutic agent.

91. (New) A method to treat a disease affecting at least one of the choroid, retina, or uvea of an eye in a patient having diabetic retinopathy, age related macular degeneration, or retinitis pigmentosa, the method comprising administering to the eye a composition comprising between 0.1% (w/w) to 5% (w/w) of a therapeutic agent selected from the group consisting of immunophilin binding compounds in a pharmaceutically acceptable topical formulation for a duration to achieve an amount of therapeutic agent in the choroid, retina, or uvea sufficient to treat the disease.

92. (New) The method of claim 91, wherein the therapeutic agent is selected from the group consisting of rapamycin, tacrolimus, everolimus, pimecrolimus, SDZ-RAD, CCI-779, AP23841, ABT-578, and analogs and derivatives thereof.

93. (New) The method of claim 92, wherein the therapeutic agent is selected from the group consisting of rapamycin and tacrolimus.

94. (New) The method of any of claims 91, 92 or 93, wherein the composition comprises 2% of the therapeutic agent.

95. (New) The method of claim 93, wherein the therapeutic agent is tacrolimus and the composition comprises 1% of the therapeutic agent.

96. (New) The method of claim 76, wherein the patient has age related macular degeneration.

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97. (New) The method of claim 77, wherein the patient has age related macular degeneration.

98. (New) The method of claim 78, wherein the patient has age related macular degeneration.

99. (New) The method of claim 79, wherein the patient has age related macular degeneration.

100. (New) The method of claim 80, wherein the patient has age related macular degeneration.

101. (New) The method of claim 81, wherein the patient has age related macular degeneration.

102. (New) The method of claim 82, wherein the patient has age related macular degeneration.

103. (New) The method of claim 83, wherein the patient has age related macular degeneration.

104. (New) The method of claim 86, wherein the patient has age related macular degeneration.

105. (New) The method of claim 87, wherein the patient has age related macular degeneration.

106. (New) The method of claim 88, wherein the patient has age related macular degeneration.

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107. (New) The method of claim 89, wherein the patient has age related macular degeneration.

108. (New) The method of claim 90, wherein the patient has age related macular degeneration.

109. (New) The method of claim 76, wherein the patient has diabetic retinopathy.

110. (New) The method of claim 77, wherein the patient has diabetic retinopathy.

111. (New) The method of claim 78, wherein the patient has diabetic retinopathy.

112. (New) The method of claim 79, wherein the patient has diabetic retinopathy.

113. (New) The method of claim 80, wherein the patient has diabetic retinopathy.

114. (New) The method of claim 81, wherein the patient has diabetic retinopathy.

115. (New) The method of claim 82, wherein the patient has diabetic retinopathy.

116. (New) The method of claim 83, wherein the patient has diabetic retinopathy.

117. (New) The method of claim 86, wherein the patient has diabetic retinopathy.

118. (New) The method of claim 87, wherein the patient has diabetic retinopathy.

119. (New) The method of claim 88, wherein the patient has diabetic retinopathy.

120. (New) The method of claim 89, wherein the patient has diabetic retinopathy.

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121. (New) The method of claim 90, wherein the patient has diabetic retinopathy.